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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,293	05/09/2005	Fritz Magerl	LUD-PT015 (PA1144+45US)	1069
3624	7590	08/13/2007	EXAMINER	
VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103			SIGLER, JAY R	
		ART UNIT	PAPER NUMBER	3709
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/534,293	MAGERL ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Jay R. Sigler	3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05/09/2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-23 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05/09/2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                        |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/09/2005</u> . | 6) <input type="checkbox"/> Other: _____.  |

## **DETAILED ACTION**

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters:
  - a. "2" and "12" have both been used to designate the elastomer (FIG. 10 and 12);
  - b. "3" and "4" have been used to designate both arrows (FIG. 1) and receptacles (FIG. 2 to 13);
  - c. "6" has been used to designate both an arrow (FIG. 2) and the supply hose (FIG. 4);
  - d. "12" has been used to designate both the leading edges (FIG. 6) and the elastomer (FIG. 7 to 12).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either

"Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 9'. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. The abstract of the disclosure is objected to because it should not repeat information given in the title and it should avoid using phrases which can be implied, such as "The disclosure concerns". Correction is required. See MPEP § 608.01(b). The following: "The invention concerns" should be removed from the first sentence.

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5. The disclosure is objected to because of the following informalities:

- a. [0031], line 3 should be changed from "effectively be prevent the filling" to -- effectively prevent the filling --;
- b. [0071], "9" is used for both "peg or screw" and "nut";
- c. [0080], -- 17 -- should be after "air bubble".
- d. [0091], There is no "Figure 16"

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Regarding claims 1, 3 and 17, the phrases "can be" and "such as" render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
- b. All other claims are dependent on claim 1 and are therefore indefinite.
- c. In view of the fact that the supply hose, filling material, and elastomer are further limited by dependent claims 4, 6, and 11-16, claims will be examined under the assumption that the supply hose, filling material, and elastomer are

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intended to be required in the claimed invention. Appropriate action is still required for claim rejections under 35 U.S.C. 112.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, 17, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Barber (U.S. Patent 5,236,460).

For claims 1-8, 17, and 21-23 Barber teaches:

a. Concerning claim 1, an implant that can be used in procedures for stiffening the vertebral column, the implant comprising an enclosed hollow body 11 which includes at least two movable open receptacles 13 and 23, oriented toward one another which interlock (Figure 3, the two parts fit together), and can be spread apart by inserting a filling material (Column 3, Lines 18 and 19).

b. Concerning claim 2, there are two open receptacles which interlock (Figure 3, the two parts fit together).

c. Concerning claim 3, the implant also, can be connected to a supply hose (Figure 5 and 6, 55 is referred to as a injecting tool in Column 3, Line 5 which is taken to be embodied by a supply hose).

- d. Concerning claim 4, the other end of the supply hose is adapted for connection to a device 59 and 61 used to generate a filling pressure.
- e. Concerning claim 5, the implant has an opening 17, for connecting the supply hose, which is also used for attaching an instrument (55 is also used as an installation tool, Column 6, Line 66 and Column 3, Lines 11-13) used to insert the hollow body.
- f. Concerning claim 6, the filling material is made of a tissue compatible, liquid (Column 3, Lines 52-54) or initially liquid phase, self-hardening material (Column 3, Lines 1-21).
- g. Concerning claim 7, the hollow body is structured on one part or over an entire surface thereof (11 including 21, 31, 33, and 37 as structures).
- h. Concerning claim 8, the receptacles forming the hollow body are sealed (Column 2, Lines 24-25) with one another.
- i. Concerning claim 17, the hollow body is compressed to minimum height before implantation (Figure 2) and a device 55 is attached to the hollow body to expand the hollow body after implantation (Column 3, Lines 18-19).
- j. Concerning claim 21, the receptacles of the hollow body can be pressurized and have a form of a partial cylinder 23 and 13, whereby base and cover plates are included that are even or slightly arched and are positioned parallel or slightly slanted relative to each other 19 and 29.
- k. Concerning claim 22, the implant includes a connection 17 for attaching an implantation instrument 55.

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- I. Concerning claim 23, a surface of the implant is structured (11 including 21, 31, 33, and 37 as structures).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) as applied to claim 1 above, and further in view of Strnad et al. (U.S. Patent 6,296,665).

Barber teaches the claimed invention as shown in paragraph 9(a) above including the receptacles being adjustable to each other, but does not teach whereby the adjusting movement is limited to a certain area, which ensures a mutual overlapping of the receptacles (claim 9) and that this area is limited though a screw in one of the two receptacles catching in a slit in the other of the two receptacles (claim 10). Strnad et al. teaches a pin 118 carried by the upper portion 102 that is disposed in a slot 120 of the lower portion 106 for the purpose of preventing the upper and lower portions from becoming disconnected, and thus the adjusting movement of the upper and lower portions is limited to a certain area that ensures a mutual overlapping of the portions. It would have been obvious to someone of ordinary skill in the art at the time the invention was

made to provide a pin, or for this purpose a screw would be functionally equivalent, to the inner body 23 and a slot, or slit, to the lower body 13 of the invention of Barber, in view of Strnad et al., in order to prevent the upper and lower portions from becoming disconnected, and thus limiting the adjusting movement and ensuring a mutual overlapping of the receptacles.

12. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) as applied to claim 1 above, and further in view of Ferree (U.S. Patent 6,419,704).

Barber teaches the claimed invention as shown in paragraph 9(a) above. Barber teaches a resin or other liquid as a filling material, but not specifically an elastomer (Claim 11). Ferree teaches that an implant can be filled with an elastomer, amongst other materials (Column 5, Lines 42-45), which will enable the implant to cyclically compress and expand in a manner similar to the disc material being replaced (refer to Abstract). It would have been obvious to someone of ordinary skill in the art at the time the invention was made to use an elastomer as the filling material in the invention of Barber, in view of Ferree, in order to enable the implant to cyclically compress and expand in a manner similar to the disc material being replaced. As for the limitations in claims 12 and 13 that the elastomer is either completely or partially filling the space and that it is either loosely or firmly fitted to an inner side wall of the hollow body, such would naturally flow from the device of Barber, in view of Ferree, since a filling material

must either completely or partially fill a space and the material will either firmly or loosely be fitted to the inner walls of said space.

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) as applied to claim 1 above, and further in view of Ferree (U.S. Patent 6,419,704) and Collaran (U.S. Patent 6,258,126 B1).

Barber teaches the claimed invention as shown in paragraph 9(a) above and an elastomer is shown to be an obvious filling material as shown in paragraph 12 above. Barber or Ferree do not teach the inner surface of the upper and bottom wall of the interlocking receptacles of the hollow body penetrating into the filling material. Collaran teaches upper and lower walls that clearly penetrate the elastomer filling (Fig 1) to mechanically mate the cushioning member with the body members (Column 4, Lines 17-24). It would have been obvious to someone of ordinary skill in the art at the time the invention was made to have the inner surface of the upper and bottom wall of the interlocking receptacles of the hollow body penetrate into a elastomer filling material in the invention of Barber, in view of Ferree and Collaran, for reasons shown in paragraph 12 above and to mechanically mate the elastomer to the body members.

14. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) as applied to claim 1 above, and further in view of Ferree (U.S. Patent 6,419,704) and Powell (U.S. Patent 4,517,844).

Barber teaches the claimed invention as shown in paragraph 9(a) above and an elastomer is shown to be an obvious filling material as shown in paragraph 12

above. Barber or Ferree do not teach an air bubble added to the filling material (claim 16). Powell teaches that elasticity can be changed by air bubbles in a material. It would have been obvious to someone of ordinary skill in the art at the time the invention was made to add an air bubble to the filling material of the invention of Barber, in view of Ferree and Powell, in order to change the elasticity to allow for the implant to compress and expand in a manner similar to the disc material being replaced. Concerning claim 15, a space below the elastomer would be functionally equivalent to an air pocket, or air bubble, and thus would change the elasticity to allow for the implant to compress and expand in a manner similar to the disc material being replaced.

15. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460) as applied to claim 1 above, and further in view of Kuntz (U.S. Patent 4,349,921).

Barber teaches the claimed invention as shown in paragraph 9(a) above, but does not include a wedge shaped insertion end. Kuntz teaches a wedge shaped end 16 to facilitate insertion into the intervertebral space (refer to Abstract). It would have been obvious to someone of ordinary skill in the art at the time the invention was made to add a wedge shaped insertion end to the invention of Barber, in view of Kuntz, in order to facilitate insertion into the intervertebral space.

16. Claims 19 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (U.S. Patent 5,236,460).

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Barber teaches the claimed invention as shown in paragraph 9(a) above except for the implant being manufactured from a metal, polymer or a composite material or using a material that would produce radiological shadows. However, metals, polymers, composite materials and materials that would produce radiological shadows are art recognized materials for implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the implant of a metal, polymer or a composite material or using a material that would produce radiological shadows, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416.

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In particular, Parsons et al. (U.S. Patent 5,545,229) teaches coating an implant to enhance fixation of the prosthesis to bone and Kretschmer et al. (U.S. Patent 6,352,556) teaches a screw 5 in one component of the prosthesis to expand said component to tightly mate with a second component and, therefore, a relative displacement of the components is prevented (Column 3, Lines 10-18).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jay R. Sigler whose telephone number is (571) 270-

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3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 5 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 09 August 2001

jrs

  
SAMCHUAN C. YAO  
SUPERVISORY PATENT EXAMINER